

This brief report captures the comments and suggestions of field inspection personnel regarding the Sanitation Directive (11,000.1) released on 1-25-00. Telephone interviews were conducted with field inspection personnel, including veterinarians and inspectors. Interview results are reported as follows: 1) the key findings, 2) the clarity of each of the main content sections of the Directive, 3) general comments, 4) the Questions and Answers section, 5) obtaining help for clarification, and 5) distribution.

## Key Findings

Field inspection personnel felt the Directive format was good and the content was generally clear, although some questions on content remain. Respondents particularly appreciated the new format and commented that the use of plain language and the question and answer format was a great improvement to the "legalese" tone of previous Directives. Some of the greatest confusion and controversy centered on lighting, water, and lavatory facilities.

In some cases, respondents said the intent of the Directive was clear (that is, to inspect for proper sanitary conditions), but that the terms for compliance used in the regulations were vague. This vagueness, combined with an absence of standards, would lead to controversy with plant management. Having District Office backing for individual field inspection personnel determinations was seen as most helpful in reducing controversy with plants.

Respondents found opportunities for presentations and discussion on the Directive to be extremely helpful and would like to have more meetings with supervisors and Field Operations staff. Half of the personnel who sought individual assistance were not satisfied.

## Clarity of Main Sections

Most respondents found the content clear and format good. However, some sections were rated relatively clearer by field inspection personnel than others. Comments from those who had questions, or found some material difficult are provided below for Directive sections and the Questions and Answers segment.

In this report, we will discuss the individual sections and topics of the Directive in order of their clarity, from least to most.

### Section VIII -- C. Light, pages 5-6

The section of the Sanitation Directive covering establishment lighting was rated as "unclear" by the highest percentage of respondents (close to half) of any of the sections.

- Field inspection personnel found the language confusing on page 6, where it referred to not rescinding the regulations on lighting. To field inspection personnel, it appears that FSIS is, in actuality, abolishing the regulations.
- It was confusing when language such as "adequate" and "sufficient" was used here and in other parts of the Directive, as these do not supply an absolute standard, as was previously available.
- The question was raised as to whether field inspection personnel could ask for more than the old standard of 50 candle power if the field inspection personnel thought the level of 50 was "inadequate."

### Section VIII – F. Water, pages 8-10

Under one-fourth of the respondents rated this section as "unclear."

- It was not clear how often water samples would be required. Is a

certificate regarding potable water that is older than one year acceptable?

- How is the word "transparent" used on page 9: "The water performance standard makes *transparent* the current requirement that potable water comply with EPA... regulations."?
- Field inspection personnel do not necessarily know the EPA National Drinking Water Standards.
- If the plant fails water reuse activities as documented by HACCP, is this a 06D01 or does this fall under 03?
- It may be easier to understand part of this section (page 8, 1. (1)) if there are separate paragraphs on municipal water and well water.

## Section VIII – G. Lavatory, pages 10-11

Some respondents rated the material on lavatories "unclear." Their typical questions follow.

- What standards can field inspection personnel use for the required number of toilets per employee? Is the old handbook obsolete?
- Is the old blueprint handbook obsolete?
- One respondent feared, that with no OSHA standard, the plant will not supply sufficient lockers for the number of employees.

## Section VIII -- I. Sanitary operations, pages 12-13

Some field inspection personnel found the material in this section to be "unclear."

- There is some confusion over paragraphs (a) and (b) on page 12 as to

whether pre-operational or operational sanitation was intended.

- Is this meant to be a 06D or 01A?
- Field inspection personnel found the direction concerning cleaning "as frequently as necessary" to be vague.
- The field inspection personnel do not know what FDA requires for chemical sanitizers (see page 13, paragraph 3).
- This section of the Directive seems to conflict with SSOPs, therefore a distinction needs to be drawn between the two.

## Section VIII -- H. Equipment pages 11-12

Some of the field inspection personnel found the material in this section to be "unclear."

- What is an approved disinfectant? There seems to be a contradiction on page 11, section H.2., as to whether a plant can use either 180 degree Fahrenheit water or instead, use a disinfectant.
- In the absence of absolute standards, new field inspection personnel will need more information. For example, a new inspector had recently approved porcelain, but FSIS had previously specified that porcelain is not a material sufficient to prevent adulteration.
- Since this Directive supplies no specifics as to equipment, a plant can now use wood even if it is impossible to clean and if the agency had required plants to use utensils with plastic handles in the past. Therefore, field inspection personnel would like more information on acceptable materials.

- This section of the Directive appears to overlap with SSOP requirements.
- It appears that it is now up to the plant as to what equipment they will use, as field inspection personnel no longer have authority in this area.

The following eight sections of the Directive were rated “unclear” by very few field inspection personnel, yet there were some questions and comments on clarity, as well as praise regarding clarity and usefulness.

## **Section VIII – A. Grounds, page 3-4**

- Can a plant now use bait boxes if they feel they are safe -- even though Agency field inspection personnel had previously instructed plants to remove all bait boxes?

## **Section VIII – E. Plumbing and Sewage, pages 6-7**

- This section was rated as fairly clear, however, field inspection personnel asked what is the meaning of “sufficient.”

## **Section IX -- enforcement actions, pages 15-17**

- For some, it is unclear which trend indicator to choose to correctly identify a noncompliance.
- When considering direct vs. indirect product contaminants, field inspection personnel commented that it is important to remember that bad product may be shipped while we wait for District Office approval. It is disconcerting to lose control of product.
- It is important to enforce SSOPs when product is contaminated.

## **Section VIII -- Employee Hygiene, page 14**

- Clarify what are “unhygienic practices.”
- This Directive contains no references to head covers.
- This section is too vague. Therefore, field inspection personnel can no longer require a plant to change employee smocks each day. So, employees at one plant now wear smocks covered with blood for the entire week before they are cleaned.
- One respondent found this Directive section to be very helpful and he was able to use it to write an NR.

## **Section VIII -- B. Construction, page 4-5**

- The material that covers inedible product placed in the edible cooler is not clear. There is a conflict between section B. (4) on page 4 (“Rooms ... in which edible product ... is stored must be separate ..from rooms ... in which inedible product is ... stored, to the extent necessary to prevent product adulteration ...”) and the second to the last sentence of this section on page 5 which states that we should “check areas where both edible and inedible products are ...stored to ensure that they are kept separate.”
- It would be helpful to define “sound” and “sufficient,” otherwise these terms are open to the field inspection personnel’s interpretations.

## Section VIII – D. Ventilation, page 6

- Field inspection personnel may differ on adequate ventilation -- some have zero tolerance, while others are more lenient.
- One respondent commented that he had informed one plant that they had a strong ammonia smell. However, if the plant does not cooperate in eliminating the smell, he cannot enforce his ruling unless the plant experiences a problem in implementing its HACCP plan.
- One inspector had a question regarding eggs, as positive ventilation was not mentioned in the section.
- The writing in this section leaves a lot of room for interpretation by the field inspection personnel. However, this section was rather vague in the previous Directive as well.

## Section VII -- Compliance/Noncompliance with the Sanitation Performance Standards, page 2

- Field inspection personnel would like more specific information on how NRs should be written.
- Field inspection personnel are confused with the direction to write simple NRs, yet with sufficient detail.
- There does not appear to be a drastic change in the material in this section from the previous Directive.

## Section VIII -- K. Custom Exempt Facilities, pages 14-15

- Over half of the field inspection personnel surveyed said this material was not applicable to their work. The remainder of the respondents felt the

section was clear. No one rated it as "unclear."

- Does this Directive combine 06B -- custom exempt -- into 06D, page 14?

## Questions and Answers Segment, page 35

- Most field inspection personnel found the questions and answers to be really helpful, as well as the format in which they were presented. One said that this section provides as much help as can be given at this point in time, all things considered.
- Even though this section is helpful, it provides less guidance than the former Directive. Therefore, many field inspection personnel are still working from old references and turning to more experienced staff for guidance.
- One respondent would like to see the first part of the chemical list reinstated.

## General Comments on the Directive

- In all, this is a good Directive; it is simple and broad; very clear; and a vast improvement over previous Directives.
- Field inspection personnel would like to have more work unit meetings for presentations and discussion, especially with a Directive of this magnitude. Such meetings with supervisors, Circuit Supervisors, and Field Operations staff were found to be extremely helpful.
- Since the Sanitation Directive is so vague, field inspection personnel are finding that they have to make up for the lack of specific direction in their circuit meetings. That is, without explicit standards, field inspection personnel are

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turning to each other and their supervisors to determine what is acceptable. There is concern that this will lead to different standards in different areas of the country.

- There is a fear that the knowledge about sanitation currently evident among plant managers and the field inspection personnel who had instructed them will erode over time, making it more difficult to define what is adequate, and leading to unsanitary plant conditions.
- There is concern that field inspection personnel may only take action on sanitary problems if the HACCP system breaks down in a plant.
- The Agency should consult with inspectors in the field rather than just obtaining comments from veterinarians when writing new Directives.
- The lack of absolute standards, such as the one for lighting, was viewed as a drastic change from the previous Directive, and raised concerns that field inspection personnel would not be able to justify their regulatory actions.
- Because the Directive is too vague, respondents feel it will lead to arguments with the plant.
- Respondents feel that, with this Directive, power has been taken away from the field inspection personnel.
- With this new Directive, field inspection personnel believe they no longer have authority over plant sanitation. There does not appear to be authority to regulate many aspects of plant sanitation anymore, such as construction, lighting, etc.
- Field inspection personnel should have authority to define "sanitary."
- When considering the regulations, does "should" mean "required?"
- Field inspection personnel need a better definition between 06D and 01A and 01B SSOPs.
- There is a concern that the paperwork in the plant does not reflect the reality of operations.
- The Agency should create a search engine for the FSIS Web Site to allow field inspection personnel to search for specific references in regard to this Directive.
- Attachment III, which provides the regulations cross-reference chart, is good.
- FSIS needs to supply inspection personnel in the field with any regulations mentioned in the Directive that field personnel do not currently have in their possession.
- Field inspection personnel need a list of regulations that do not apply anymore.
- Respondents said it is now even more important to have the District Office backup field staff because then the plant will listen.
- Respondents are concerned because it costs a lot to keep plants clean, and plants will want to cut costs that will result in dirty conditions.
- Respondents noted that plants are incorporating previous FSIS requirements into their SSOPs and GMPs, probably not only to keep the plants clean, but also to avoid Agency intervention if these elements are not in their HACCP plan.

## Obtaining Help for Clarification

- Close to half of the field inspection personnel reported that they had sought help to clarify the Directive. Of those that sought help, more than half of the respondents turned to their supervisory personnel for assistance; under half turned to their colleagues for clarification; and a couple turned to the Technical Services Center. When asked if this assistance was sufficient to answer their issues of concern, less than half of the respondents who had sought assistance indicated that it had helped.

Topics for which assistance was sought include:

- What is the difference between "performance standards" and former "command and control" -- especially enforcement action and correct codes? Plants still must be clean.
- Can wooden utensils be cleaned?
- Assistance was requested to clarify terms, as the regulations were felt to be difficult to enforce without specific standards.
- How to choose correct trend indicators.
- What is the purpose of the Consumer Safety Officer if the plant defines "sanitary?"

## Distribution

- The majority of the field inspection personnel received the Directive within two weeks. A number of field inspection personnel had received an advance draft of the Directive earlier in January. Most obtained the Directive by regular mail, while a few others received it via email.

## Learning the content of the Directive

- The field inspection personnel learned the content of the Directive in two main ways: approximately half of the field inspection personnel reported that their supervisors explained the new Directive during meetings or discussions summarizing the new aspects. A little less than half of the field inspection personnel learned the contents of the Directive by reading it. In one case, FO made a presentation in the field, and in another case, a colleague explained the Directive.

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